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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,045

09/26/2003

Stephen J. Brown

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HEALTH HERO NETWORK, INC.
2400 GENG ROAD, SUITE 200
PALO ALTO, CA 94303

EXAMINER

HU, KANG

ART UNIT

PAPER NUMBER

3715

MAIL DATE

DELIVERY MODE

09/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/673,045	Applicant(s) BROWN ET AL.	
	Examiner KANG HU	Art Unit 3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,50-52,55-62,64,65,68-79,81-84 and 96-122 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,50-52,55-62,64,65,68-79,81-84 and 96-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/2009 has been entered. Claims 1-47, 49, 53, 54, 63, 66, 67, 80, 85-95 were previously cancelled, claims 116 – 122 has been added, claims 48, 50-52, 55-62, 64, 65, 68-79, 81-84, and 96-122 are currently pending in the application.

Terminal Disclaimer

2. Previously applicant's representative filed terminal disclaimer on 8/21/2007 to overcome the obviousness double patenting rejection made in non-final office action on 5/21/2007, the examiner indicated in final rejection 10/30/2007 that the terminal disclaimer has been reviewed and is accepted and withdrew the obviousness double patenting rejection. The statement was an error as the terminal disclaimer had not been reviewed at that time. The terminal disclaimer has been reviewed and is not accepted because the current application does not have the same assignee as U.S. patent 5,601,435 and therefore improper. The obvious double patenting is reinstated until a proper terminal disclaimer is filed on record.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Claims 48, 50-52, 59, 61, 75-79, and 81-84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 5, 6, 11, 12, 14, 15, and 17 of U.S. Patent No. 5,601,435. Claims 48, 50, 51, 52, 59, 61, 75, 76, 77, 78, 79, 81, 82, 83, and 84 most closely relate to claims 1, 5, (1 and 5), 6, 3, (1 and 2), 11, 12, 14, 15, 17, 11, 12, 15, and 17, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly pending claims represent an obvious variation of the patented claims. With respect to claim 48 which correlates to patented claim 1, the claims commonly show the features of a multimedia processor to provide audio and visual signals, a physiological data monitor to provide physiological parameter of a user, a patient isolating circuit and a program controller to retrieve external information. The patented claim however does not recite a blood glucose monitor. However, a physiological data monitor is the a generic term which includes the field of all blood glucose monitors for measuring glucose levels. On of ordinary skill in the art could not practice the more specific version presently claimed without infringing on the more generic version. The remaining claims 50-52, 59, 61, 75, 76, 77, 78-79, 81-84 recites similar limitations as those provided in the patent 5,601,435 and are identified above.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 48, 50-52, 55-62, 64, 65, 68-79, 81-84, 96-122 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Re claims 48 and 81, the claims recite “at least one physiological data monitor configured to ... operate while being physically separated from said processor and outside a first housing containing said processor” and “the electrically isolating interface device is neither entirely disposed within said first housing containing said processor nor any housing containing said physiological data monitor”

Re claims 51, 62 and 75, the claims recite “a processor ... configured to operate while being physically separated from said glucose monitor, said glucose monitor being disposed outside said housing containing said processor” and “an interface device coupled between the blood glucose monitor and the processor... “

The closest teaching is found in applicant's amendment to the specification made on 10/17/2005, page 8, 2nd paragraph. The specification is amended to recite "the multimedia processor 801 is also coupled to a physiological data monitor 810. The physiological monitor is coupled to the user's body to obtain electrical signals representative of a physiological parameter... Preferably, the interface device comprises the patient isolating circuit described above by being integrally

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housed within the same housing, however, the patient isolating circuit may be separately housed or incorporated into the physiological data monitor.”

And page 8 of specification originally filed by the applicant, paragraphs 31 and 33 of the applicant’s pgpub recites "file server and multimedia processor can also contact each other via wireless communication networks, telephone networks, or any other suitable network" and "input device comprising numerous momentary contact push buttons... input device is a standard wireless communication means which sends command signals to multimedia processor to be processed”

The specification as originally filed and amendment to the specification do not provide support for having a physiological data monitor physically separate from the processor as claimed in each of the independent claims 48, 51, 62, 75 and 81. Furthermore, the teaching of an interface device reinforces the examiner's position that there is a physical connection between the processor and the monitor.

Claims 50, 52, 55-61, 64, 65, 68-74, 76-79, 82-84, and 96-122 are rejected for their incorporation of the above through their dependency of claims 48, 51, 62, 75 and 81.

Priority

7. Applicant’s claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

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The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 09/971,785, 09/119,546, 08,953,883, 08/757,129, 08/334,643, 08/857,187, 08/247,716, and 08/958,786 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claims 48, 51, 62, 75 and 81 each recites similar limitations of having a physiological data monitor physically separated from the processor as explained above, the examiner failed to find any support for the limitations from the prior-filed application. The applicant is therefore only provided with the priority date of 9/26/2003, the filing date of the current application.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 48, 50, 51, 55-62, 64, 68-79, 81-84, and 96-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 5,307,263 in view of Miwa (US 4,974,607).

Re claims 48, 51, 62, 75 and 81, Brown teaches a blood glucose monitoring system for monitoring a blood glucose level and for providing health-related information comprising:

a) a display device including a display screen which displays the blood glucose level as measured (Brown, col 7, lines 29-47);

Brown does not explicitly teach of an audio speaker; Brown teaches of a game boy (Brown, col 9, line 1-3), the examiner takes **official notice** that it is old and well known that a game boy has audio speakers. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the monitoring system to include a audio speaker to provide audible notifications to the user.

c) a processor configured to provide audio and visual signals to the audio speaker and display device respectively (Brown, col 8, lines 1-14);

d) at least one built-in memory including read-only digital memory (ROM) or writeable digital memory (RAM), or both (col 17, lines 1-7), having stored therein operation data and operation software routines for:

i) controlling the blood glucose monitoring system (Brown, col 10, lines 1-25);

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ii) comparing the blood glucose level as measured with stored measurements (Brown, col 11, line 50: statistical data)

iii) performing one or more further processing functions in response to the comparing (Brown, col 11, lines 50-63: adapts handheld microprocessor unit for supplying control signals and signals representative of food intake or other useful information).

iv) connecting to a remotely located computer in response to receiving an address of the remotely located computer from a memory card; (Brown, col 13, lines 1-16)

v) receiving the health-related information from the remotely located computer (Brown, col 13, lines 1-16);

e) at least one physiological data monitor configured to

i) provide a measurement signal representative of a physiological parameter of a user (blood glucose monitor) and

Brown does not teach that the physiological data monitor is physically separated from the processor, Miwa teaches of having a patient's medical data wireless transmitted to the processor (Miwa, col 4, lines 38-56). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brown to wirelessly transmit the physiological parameter of the user to allow user freedom of movement during the monitoring process.

f) an interface device coupled between the processor and physiological data monitor to at least isolate electrically the physiological data monitor from the processor, wherein the electrically isolating interface device is neither entirely disposed within said first housing containing said

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processor nor any housing containing said physiological data monitor (Brown, col 5, lines 20-26: the monitoring unit can be constructed as a plug-in unit having an electrical connector that mates with a connector mounted within a region that is configured for receiving the monitoring unit – the interface cable is not disposed within data monitor or the processor unit, and when the cable is unplugged, it isolate electrically the physiological data monitor from the processor);

and g) an input device in communication with the processor and configured to

i) receive an input from the user

ii) enable the user to

1) make selections and

2) control one or more user functions of the blood glucose monitoring system

and iii) provide a control signal to the processor based upon the input, thereby to cause the health related information to be provided to the user based upon the measurement signal representative of the blood glucose level and the control signal, wherein the physiological parameter includes the blood glucose level and the physiological data monitor includes a blood glucose indicator (Brown, col 5, lines 1-5; col 13, lines 1-16).

Brown further teaches

Re claims 50, 64, 79, 84, a signal receiver for receiving the measurement signal representative of the blood glucose level from the at least one physiological data monitor; a converter for converting the measurement signal as received into a form acceptable to the processor, and a processor controller for controlling the processor (Brown, col 4, lines 49-55).

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Re claims 55 and 68, the input device is hand-held (Brown, col 5, lines 26-30: handheld microprocessor-based unit).

Re claims 56 and 69, the input device received the input from the user through at least one push button switch (Brown, col 5, lines 26-30: buttons or keys).

Re claim 57 and 70, the health related information provided to the user includes moving images displayed on the display screen (Brown, col 5, line 60 – col 6, line 5).

Re claim 58 and 71, comparison of measurements of blood glucose level with previously stored measurements of the blood glucose level (Brown, col 11, lines 40-55).

Re claim 59 and 72, health related information provided to the user includes educational information (Brown, col 5, line 68).

Re claim 60 and 73 and 117, the blood glucose monitoring system is configured to store particular information on the at least one built-in memory for later retrieval (Brown, col 16, line 65 – col 17, line 9).

Re claim 61, 74 and 77, the display device is a television display is encompassed by the teaching of a display, the processor has at least one removable memory (Brown, col 8, lines 25-35).

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Re claim 76 and 82, the processor comprises a video game console (Brown, gameboy)

Re claim 78 and 83, a CD-ROM drive; and an interchangeable compact disk removably coupled to the CD-ROM drive for providing additional functionality to the processor (col 5, lines 1-5: analogous to the teaching of a removable program cartridge).

Re claims 96, 100, 104, 108, 112 one or more communication ports configured to connect the blood glucose monitoring system to an “information superhighway” (Brown, col 11, lines 16-30).

Re claims 97, 101, 105, 109, 113 slot for accepting a flash memory card (Brown, col 8, lines 14-30: program cartridge).

Re claims 98, 102, 110, blood glucose monitoring system is configured for downloading particular information obtained from the user to a separate computer (Brown, col 6, lines 45-58).

Re claims 99, 103, 107, 111 115, 118, 120, at least one built-in memory further has stored therein alarm software routines for triggering an alarm if the blood glucose level as measure falls outside a predetermined range (Brown, col 11, lines 40-63).

Re claims 106, 114, downloading particular information obtained from the user to a separate server (Brown, col 6, lines 45-58)

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Re claims 116, operational data and the operation software routines are configured to guide the user through additional measurements based on the comparing (Brown, col 11, lines 40-63).

Re claims 119, ask questions based on the comparing (Brown, col 11, lines 15-17).

Re claims 121 and 122, Brown does not teach of an input device is in wireless communications with the processor and physiological data monitor and the input device are in a second housing separate from the first housing containing the processor. Miwa teaches of having multiple sensors wirelessly transmit physiological data to the processor (col 2, lines 35-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brown to wireless transmit communication in order to allow the patient mobility during the monitoring process.

10. Claims 52 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 5,307,263 in view of Miwa (US 4,974,607) as applied to claims above, and further in view of Holmes II et al. (US 5,371,687).

Re claims 52 and 65, Brown does not teach of an interface device utilizing optical isolation, Holmes teaches interface device utilizes optical isolation (Holmes, col 4, lines 7-27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Brown to use an optical isolation interface to prevent any unwanted feedback.

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Response to Arguments

Applicant's arguments with respect to claims 48, 50-52, 55-62, 64, 65, 68-79, 81-84, and 96-122 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KANG HU whose telephone number is (571)270-1344. The examiner can normally be reached on 8-5 (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-262-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kathleen Mosser/
Primary Examiner, Art Unit 3715

/K. H./
Examiner, Art Unit 3715